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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,889	01/25/2002	Thomas C. Hart	WFU.99-35	8219

110 7590 09/15/2003

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EXAMINER

MYERS, CARLA J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,889

Applicant(s)

HART, THOMAS C.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-10 and 13-38, drawn to nucleic acids and methods of detecting nucleic acids.

Group II, claim(s) 11, drawn to proteins.

Group III, claim(s) 12, 39 and 40, drawn to antibodies.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

Under PCT Rule 37 CFR 1.475, Applicant is entitled to an examination of the first product, method of making said product and method of using said product. In the instant Application, the methods of groups II and III constitute additional and distinct methods. Accordingly, restriction of groups I-III is proper. Furthermore, the molecules of groups I, II and III do not share a corresponding structural property. The special technical feature of the nucleic acids of Group I is the identity of its monomers which are nucleotides and which determine its structure, properties and function. In contrast, the special technical feature of the proteins of Group II are its amino acid monomers, which determine its structure, properties and function which are arranged in a specific 3-dimensional structure. The special technical feature of the antibodies of group III are also its amino

acid monomers. However, in an antibody, the amino acids are arranged in a specific tertiary structure wherein four subunits (2 light chains and 2 heavy chains) are joined via disulfide bonds. The antibodies of group III differ from the proteins of group II with respect to their amino acid sequence, secondary and tertiary structure and their functional activities. While antibodies bind to specific target antigens and function in immunological reactions, such that they may neutralize an antigen, polynucleotides do not have these functional activities. Proteins may be used for therapeutic purposes or in ligand binding assays. Further, while nucleic acids may be used in hybridization assays, antibodies and proteins may not be utilized in hybridization assays. Additionally, the methods of group I do not require the proteins of group II or the antibodies of group III.

Further Requirement to Elect a Mutation

3. In addition, each invention detailed above reads on patentably distinct inventions drawn to multiple polymorphisms. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. Although the chemical compounds share a common structure in that they are nucleic acids (with respect to group I) or are all proteins (with respect to group III) or are all antibodies (with respect to group IV), the compounds are not regarded as being of a similar nature because all of the alternatives do not share a common property or activity. Each of the nucleic acids and proteins include a different mutation. Each mutation has a different chemical structure and imparts a different functional attribute to the nucleic acid and protein. It is

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noted that claims drawn generically to any mutation will be examined for their full scope, but claims drawn to a specific mutation will be examined only to the extent that they read on the elected mutation. **In response to the restriction requirement, Applicant must further elect a single mutation selected from the group of mutations set forth in Table 1.**

It is further noted that this is a restriction requirement and should **not** be construed as an election of species.

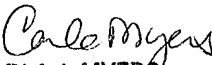
4. A telephone call was made to Kathleen Rigaut on August 28, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
September 8, 2003


CARLA J. MYERS
PRIMARY EXAMINER